

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

MAR 27 2003

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES



In re Patent Application of :  
YACCARINO III :  
Serial No.: 09/503,166 : EXAMINER PHAN  
Filed: February 14, 2000 : Group Art Unit 3738  
For: COMPOUND BONE STRUCTURE :  
OF ALLOGRAFT TISSUE WITH :  
THREADED FASTENERS :  
: *476*  
: *23*  
: *FF.17*

The Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

Sir:

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APR 03 2003  
TECHNOLOGY CENTER R3700

**APPEAL BRIEF**

**STATEMENT**

This Brief is filed in support of the Applicant's appeal of the Examiner's Final Rejection dated August 27, 2002 rejecting Claims 1-12 and 29-32. The Final Rejection was in response to Applicant's First Amendment of June 5, 2002. A Response to the Final Rejection and Notice of Appeal was timely filed on January 27, 2003.

**REAL PARTY IN INTEREST**

The party named in the caption of the brief is the real party in interest.

**RELATED APPEALS AND INTERFERENCES**

There are no other appeals or interferences known to Applicant which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

#### STATUS OF THE CLAIMS

Claims 1-12 and 29-32 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable in view of Paul et al. U.S. Patent Number 6,258,125 when combined with Reed U.S. Patent Number 5,968,047.

Claims 1-12 and 29-32 are being appealed.

#### STATUS OF THE AMENDMENTS

The Examiner issued a final rejection on August 27, 2002 rejecting the claims. A Response including a Declaration with Exhibits was made after the final rejection presenting arguments as to why the references were not valid prior art. No reply to this response has been received.

#### SUMMARY OF THE INVENTION

The present invention is directed toward a compound bone implant device of allograft bone made by combining two or more smaller bone members which have complimentary mating faces to form a compound load bearing bone structure. The mating faces prevent displacement of the bone members with respect to each other in both the longitudinal and transverse directions when an anatomical load is applied. Fastener members are placed in

axially aligned bores cut through the bone members across the mating face to hold the bone members in engagement.

#### ISSUES PRESENTED

(1) Whether the invention as defined in Claims 1-12 and 29-32 is obvious and therefore unpatentable under 35 U.S.C. 103(a) over the cited prior art references Paul et al. U.S. Patent Number 6,258,125 in view of Reed U.S. Patent Number 5,968,047

#### GROUPING OF THE CLAIMS

The grouping of the Claims 1-12 (Group 1) is directed toward a compound bone implant device made out of allograft bone made by combining two or more smaller bone members which have complimentary mating faces to form a compound bone structure. The mating faces prevent displacement of the bone members with respect to each other in both the longitudinal and transverse directions when an anatomical load is applied with each bone member defining at least one bore within its body having an axis which intersects a plane across its mating face. A threaded fastener member is mounted in the axially aligned bores and extends across the mating face to hold the first and second bone members in engagement resisting separation of the first and second bone members.

The grouping of Claims 29-32 (Group 2) is directed toward the device of Group 1 in which fastener member mounted in the bore has a treated outer surface or is in the form of a wedge nail.

## ARGUMENT

### **I. Applicant transverses the Examiner's rejection of device Claims 1-12 and 29-32 under 35 U.S.C. 103(a) as being unpatentable in view of the Paul et al. U.S. Patent Number 6,258,125 in view of Reed U.S. Patent Number 5,968,047.**

United States Patent Number 6,258,125 to Paul et al. is assigned to Synthes Corporation, a marketing partner of the Assignee (Musculoskeletal Transplant Foundation) of the present invention. Both of the respective inventors, Paul and Yaccarino work together on specific projects including this specific compound bone project and have knowledge of each others work in this area. A continuation application (not yet issued) of the Paul et al. '125 patent (presented as an Exhibit in the Amendment of June 5, 2002) has added Joseph A. Yaccarino as an inventor (Yaccarino being an inventor of the present application) and United States Patent Number 6,025,538 of which the present application is a continuation-in-part added David C. Paul as an inventor (presented as an Exhibit in the Amendment of June 5, 2002). The present application may have to add David C. Paul as an inventor depending on the final language of the claims.

Figures 6, 7, 8, 8A and 11 in the '125 patent (Figure 6 being a plan view of Figure 7) on which the Examiner's argument on obviousness were based are essentially the same as drawings made by Joseph Yaccarino prior to the filing of the provisional application number 60/095,209 on August 3, 1998 from which the 6,258,125 patent claims priority. Figures 7, 8, 8A and 11 also basically appear in U.S. Letters Patent 6,025,538 issued February 15, 2000 as Figures 10, 11, 12 and 13. The '538 patent is the parent of the present '166 application and the '166 application carried over Figure 13 of the '538 patent in its entirety as can be seen

by a comparison of the '166 application and the '538 patent. The present inventor has sworn behind the filing date of the '125 patent as seen in the 37 C.F.R. 1.131 Declaration and exhibits thereto included with the Response to the Final Rejection. A 1.131 Declaration can be used where the reference, a U.S. Patent, such as the '125 patent, with a patent date less than one year prior to applicant's effective filing date, shows but does not claim the same patentable invention. MPEP 715 As can be seen in the claims of the '125 patent attached as an Exhibit A to the Yaccarino Supplemental Declaration, the same patentable invention is not claimed. Thus, the subject matter relied upon by the Examiner namely the drawings and description of same in the '125 patent rejecting the present application is not a valid prior art reference as to the claims in question. The other figures of the '125 patent and descriptions of same do not teach, imply or obviate the present invention. Furthermore, there is no teaching of using a threaded member mounted in the axially aligned bores to hold the bone members together.

United States Patent Number 5,968,047 to Reed discloses a number of bone screws, pins, anchors and plates fabricated from bone tissue. There is no teaching of the fasteners in this reference being used to hold two or more preshaped bone members together to form a compound bone device made from smaller bone members for implantation into a surgical site to support an anatomical load applied to the device during a post operative period. There is no teaching of a load bearing device. Thus, Reed '047 singularly or in combination does not obviate the invention as presently claimed.

With respect to the Group II Claims (29-30), the same argument as noted above is applied. In addition, there is no showing in any of the prior art cited discloses a rod member

with an outer demineralized surface (Claims 29 and 30), a rod member with a knurled outer surface (Claim 31), a rod member in the shape of a wedge nail with an angular cross section (Claim 32) used to hold to bone members together to support an anatomical load. Thus, Claims 29-32 are not obviated or taught by any of the references cited, even if the Paul '125 patent was found to be a valid reference.

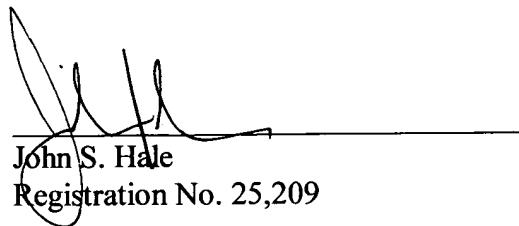
#### SUMMARY OF ARGUMENT

The respective grounds of final rejection of the claims of this application under 35 U.S.C. 103 (a) are incorrect for the reasons advanced above. Reversal thereof by the Honorable Board of Patent Appeals and Interferences is therefore requested and is earnestly solicited.

Our check in the amount of \$320.00 is attached to cover the cost of filing this Brief and two copies. Oral hearing will be requested during the rebuttal time period. If any additional fees are incurred, kindly charge the same to our Deposit Account No. 07-1340.

Respectfully submitted,

GIPPLE & HALE



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## APPENDIX

Claim 1. A compound bone device made from sterile bone tissue for implantation into a surgical site which supports an anatomical load applied to the compound bone device during a post-operative period while the implanted bone tissue is being resorbed and remodeled, comprising:

    a first bone member defining a first mating face with a plurality of spaced projections constructed and arranged to support a load in a direction that is normal to the first mating face and to receive and engage a complimentary mating face of a second bone member;

    a second bone member defining a second mating face that is complimentary to the first mating face of the first bone member constructed and arranged to support a load in the direction normal to the second mating face, said mating faces being mounted to each other so that the first and second bone members form a compound bone device which prevents displacement of the first bone member with respect to the second bone member in both a longitudinal direction and a transverse direction when an anatomical load is applied;

    each bone member defining at least one bore within its body having an axis which intersects a plane across its mating face with said bore opening on said mating face, each bore being axially aligned with a bore defined in the body of an adjacent bone member and a threaded fastener member mounted in said axially aligned bores and extending across said mating face threadably engaging at least one of said bone members to hold the first and second bone members in engagement resisting separation of the first and second bone members.

Claim 2.     A compound bone device made from bone tissue as claimed in Claim

1 wherein each bone member has a body which defines at least two angularly positioned bores which are axially aligned with the angularly positioned bores of an adjacent bone member, said bores being orientated at an oblique angle to a plane of each engaged mating surface and intersecting the plane of the mating surface and a threaded fastener member is mounted in each of the aligned bores.

Claim 3. A compound bone device made from bone tissue as claimed in Claim 1 wherein said threaded fastener member is a screw.

Claim 4. A compound bone device made from bone tissue as claimed in Claim 1 wherein said threaded fastener member is a threaded bolt.

Claim 5. A compound bone device made from bone tissue as claimed in Claim 1 wherein said threaded fastener member is a threaded rod.

Claim 6. A compound bone device made from bone tissue as claimed in Claim 1 wherein said threaded fastener member is a threaded rod with at least one nut member.

Claim 7. A compound bone device made from bone tissue as claimed in Claim 1 wherein said threaded fastener member is a threaded bolt with an associated nut member.

Claim 8. A compound bone device made from bone tissue as claimed in Claim 1 wherein one of the mating faces defines a plurality of bar members substantially parallel to the longitudinal axis of bone members and a plurality of bar members oriented transverse to the axis of the parallel bar members.

Claim 9. A compound bone device made from sterile bone tissue for implantation into a surgical site which supports an anatomical load applied to the compound bone device during a post-operative period while the implanted bone tissue is being resorbed and remodeled, comprising:

a first bone member defining a first mating face constructed and arranged to support a load in a direction that is normal to the first mating face and to receive and engage a complimentary mating face of a second bone member;

a second bone member defining a second mating face that is complimentary to the first mating face of the first bone member constructed and arranged to support a load in the direction normal to the second mating face, said mating faces being mounted to each other so that the first and second bone members form a compound bone device which prevents displacement of the first bone member with respect to the second bone member in both a longitudinal direction and a transverse direction when an anatomical load is applied;

each bone member defining at least one throughgoing bore within its body which opens on said mating face and has a stepped countersink portion at its opposite end, each bore being axially aligned with an angularly oriented bore defined in the body of the other bone member and a threaded fastener member mounted in said axially aligned bores extending across said mating face to hold the first and second bone members in engagement resisting separation of the first and second bone members.

Claim 10. A compound bone device made from bone tissue as claimed in Claim 9 wherein said threaded fastener member is a bolt and nut assembly.

Claim 11. A compound bone device made from bone tissue as claimed in Claim 9 wherein said threaded fastener member is a threaded rod with at least one nut member.

Claim 12. A compound bone device made from bone tissue as claimed in Claim 9 wherein each bone member has a body which defines at least two angularly positioned bores which are axially aligned with the angularly positioned bores of an adjacent bone member, said bores being orientated at an oblique angle to a plane of each engaged mating

surface and intersecting the plane of the mating surface and a threaded fastener member is mounted in each of the aligned bores.

Claim 29. A compound bone device made from sterile bone tissue for implantation into a surgical site which supports an anatomical load applied to the compound bone device during a post-operative period while the implanted bone tissue is being resorbed and remodeled, comprising:

a first bone member defining a first mating face constructed and arranged to support a load in a direction that is normal to the first mating face and to receive and engage a complimentary mating face of a second bone member;

a second bone member defining a second mating face that is complimentary to the first mating face of the first bone member constructed and arranged to support a load in the direction normal to the second mating face, said mating faces being mounted to each other so that the first and second bone members form a compound bone device which prevents displacement of the first bone member with respect to the second bone member in both a longitudinal direction and a transverse direction when an anatomical load is applied;

each bone member defining a bore within its body which is angularly oriented with respect to a plane across its mating face and opens on said mating face, each bore being axially aligned with an angularly oriented bore defined in the body of the other bone member and a cortical bone rod member having a partially demineralized outer surface mounted in said axially aligned bores extending across said mating face in an interference fit to hold the first and second bone members in engagement resisting separation of the first and second bone members.

Claim 30. A compound bone device made from sterile bone tissue for

implantation into a surgical site which supports an anatomical load applied to the compound bone device during a post-operative period while the implanted bone tissue is being resorbed and remodeled, comprising:

    a first bone member defining a first mating face constructed and arranged to support a load in a direction that is normal to the first mating face and to receive and engage a complimentary mating face of a second bone member;

    a second bone member defining a second mating face that is complimentary to the first mating face of the first bone member constructed and arranged to support a load in the direction normal to the second mating face, said mating faces being mounted to each other so that the first and second bone members form a compound bone device which prevents displacement of the first bone member with respect to the second bone member in both a longitudinal direction and a transverse direction when an anatomical load is applied;

    each bone member defining a bore within its body which opens on said mating face, each bore being axially aligned with a similarly oriented bore defined in the body of the other bone member and a cortical bone rod member having a partially demineralized outer surface mounted in said axially aligned bores extending across said mating face in an interference fit to hold the first and second bone members in engagement resisting separation of the first and second bone members.

Claim 31. A compound bone device made from sterile bone tissue for implantation into a surgical site which supports an anatomical load applied to the compound bone device during a post-operative period while the implanted bone tissue is being resorbed and remodeled, comprising:

    a first bone member defining a first mating face constructed and arranged to

support a load in a direction that is normal to the first mating face and to receive and engage a complimentary mating face of a second bone member;

a second bone member defining a second mating face that is complimentary to the first mating face of the first bone member constructed and arranged to support a load in the direction normal to the second mating face, said mating faces being mounted to each other so that the first and second bone members form a compound bone device which prevents displacement of the first bone member with respect to the second bone member in both a longitudinal direction and a transverse direction when an anatomical load is applied;

each bone member defining a bore within its body which is angularly oriented with respect to a plane across its mating face and opens on said mating face, each bore being axially aligned with an angularly oriented bore defined in the body of the other bone member and a cortical bone rod member with a knurled outer surface mounted in said axially aligned bores extending across said mating face in an interference fit to hold the first and second bone members in engagement resisting separation of the first and second bone members.

Claim 32. A compound bone device made from sterile bone tissue for implantation into a surgical site which supports an anatomical load applied to the compound bone device during a post-operative period while the implanted bone tissue is being resorbed and remodeled, comprising:

a first bone member defining a first mating face constructed and arranged to support a load in a direction that is normal to the first mating face and to receive and engage a complimentary mating face of a second bone member;

a second bone member defining a second mating face that is complimentary to the first mating face of the first bone member constructed and arranged to support a load

in the direction normal to the second mating face, said mating faces being mounted to each other so that the first and second bone members form a compound bone device which prevents displacement of the first bone member with respect to the second bone member in both a longitudinal direction and a transverse direction when an anatomical load is applied;

each bone member defining a bore within its body which is angularly oriented with respect to a plane across its mating face and opens on said mating face, each bore being axially aligned with an angularly oriented bore defined in the body of the other bone member and a wedge nail with an angular cross section press fit in said axially aligned bores and extending across said mating face in an interference fit to hold the first and second bone members in engagement resisting separation of the first and second bone members.